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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,936	08/30/2001	Brigitte Bathc	32301WD202	6329

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,936

Applicant(s)

BATHE ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14,16-18,21,25-29,33 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14,16-18,21,25-29 and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on October 22, 2004 has been entered.

Application Status

2. In response to the previous Office action, a Final rejection (mailed on July 28, 2004), Applicants filed an after-final amendment on September 23, 2004, which was not previously entered (see Advisory action mailed October 13, 2004), now being entered with Applicant's filing an RCE received on October 22, 2004. Said amendment amended Claim 25 and 26, cancelled Claim 34, and added new Claims 35-38. Thus, Claims 14, 16-18, 21, 25-29 and 33, and 35-38 are pending in the instant Office action and will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the foreign application 10043332.4 filed in Germany on September 2, 2000 and application 10033426.5 filed in Germany on July 10, 2001. Translations of said documents have been received on December 23, 2003.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

4. Previous rejection of Claim 25 under 35 U.S.C. § 112, first paragraph, written description, for using genes that encode a Zwa1 protein is withdrawn by virtue of Applicant's amendment.

5. Previous rejection of Claim 34 under 35 U.S.C. § 112, second paragraph, is withdrawn by virtue of Applicant's cancellation of said claim.

6. Previous rejection of Claim 25 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's amendment.

7. Previous rejection of Claim 34 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's cancellation of said claim.

Maintained - Claim Rejections - 35 U.S.C. § 112

8. Previous rejection of Claim 25 under 35 U.S.C. § 112, second paragraph, as being indefinite for "a Zwa1 protein" is maintained and altered herein; Claim 37 is added to the instant rejection. Thus, Claims 25 and 37 are rejected under 35 U.S.C. § 112, second paragraph. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the amendment has obviated the rejection; the Examiner disagrees. While it is clear what "the *Corynebacterium glutamicum* genes coding for the Zwa1 protein" would be in view of the specification, the article "a" indicates that more than one protein is in the claimed genus. Knowing nothing about Zwa1, except by way of the single example in the specification, this exact one must be the limitation in the claims for clarity.

9. Previous rejection of Claims 28-29 under 35 U.S.C. § 112, first paragraph, enabling deposit, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the following statement meets the

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criteria that “(5) the record must also contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01); this statement may be certified by Applicants or Applicants’ representative”:

“Claim 28 and 29 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that is purportedly not enabled by the specification. The Office Action asserts that the specification fails to fully comply with the requirements for deposited microorganisms.

In response, Applicants assert that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.”

Since the statement contains no indication of which “material so deposited” is governed by the above statement, said statement cannot satisfy the criteria noted above. It must be noted that DSM 14375 and DSM 13455, specifically, are governed by such a statement.

NEW ISSUES

Claim Objections

10. Claim 21 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The added limitation of limiting how increasing the copy number can be achieved does not further limit as this way is the only way to increase the copy number.

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11. Claim 28 is objected to for having improper grammar. The “of” after “Escherichia coli strain” is improper and must be deleted. Correction is required.
-

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 14, 16-18, 21, 25-28, 33, and 35-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “fermenting coryneform bacteria which produce a desired L-amino acid comprising an overexpressed polynucleotide” is confusing for the placement of the “which” clause since it separates “bacteria” and “comprising”. Clarification is required. The Examiner suggests the use of commas around the “which” clause or removing said clause and inserting the limitation in a wherein-type clause at the end of the claim.
13. Claims 14, 16-18, 21, 25-28, 33, and 35-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claims 14 and 18, the phrase “an overexpressed polynucleotide sigC” is confusing for its improper grammatical construction having two nouns, polynucleotide and sigC - unless sigC is not a noun. Clarification is required. The Examiner suggests changing the phrase to ---an overexpressed sigC polynucleotide--- wherein “sigC” can act as an adjective. If this amendment is adopted by Applicant, care must be

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taken that the antecedent basis of the term throughout the claims is not rendered unclear with by such an amendment (i.e., additional amendments may be required to identify ---said overexpressed sigC polynucleotide---). Correction is required.

14. Claims 14, 16-18, 21, 25-28, 33, and 35-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claims 14 and 18, the phrase “a nucleotide sequence of SEQ ID NO:1” and “an amino acid sequence of SEQ ID NO:2” (emphasis added) are unclear. The article “a” indicates any; however, what follows clearly defines a single sequence wherein the article ---the---should be used. Clarification is required.

15. Claims 25 and 37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases “a gene **hom** coding for homoserine dehydrogenase” and “a gene **ilvA** coding for threonine dehydratase” (emphasis added) are unclear. Are the gene names required to meet some limitation or is the enzyme functionality the only limitation? If the latter, the Examiner suggests removing the gene name from the claims. Clarification is required.

16. Claims 25 and 37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “a **gene** coding for acetohydroxy acid synthase” (emphasis added) is unclear. In paragraph [43], *ilvBN* is described as encoding acetohydroxy

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acid synthase - thus two genes (ilvB and ilvN) encode two subunits to make up the enzyme.

Clarification on how “a gene” encodes the multiple subunit enzyme is required.

17. Claims 26 and 38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how bacteria can “comprise” that which has been “eliminated”. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 25 and 37 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for overexpressing the additional genes by transforming a host cell with a vector comprising said genes and a promoter, does not reasonably provide enablement for overexpressing said additional genes by means otherwise mentioned in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To practice the claimed invention to the full extent of its scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in

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Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404).

Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

In the specification on page 12 (paragraph [0038]), means of overexpression are described. Said means include not only increasing the copy number of a gene or regulating the gene with a particular promoter, which means are enabled by the art, but also include altering the ribosome binding site, altering the lifetime of the mRNA, altering the protein so as to prevent degradation, and altering media conditions, all of which are known in the art to "overexpress" a gene in specific examples, but none of which are predictable with the genes in the claim limitations that lack specific examples in the art. The specification provides no working examples or direction for overexpression using means of ribosome binding site, altering the lifetime of the mRNA, altering the protein so as to prevent degradation, and altering media

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conditions. The nature of the invention is that these means are specific to a particular gene sequence and cannot be extrapolated from other, unrelated genes; there is no particular recipe of media that will overexpress all genes. Thus, overexpression using these methods is wholly unpredictable and not enabled by the specification or the art.

While this rejection is not applied to Claims 14 and 18, the definition of overexpression in said claims only limits "said overexpression" and does not broadly define overexpression so that such a limitation could be extended to the depend claims. The Examiner suggests removing "said" from "said overexpression" in Claims 14 and 18 to obviate the instant rejection.

Conclusion

19. Claims 14, 16-18, 21, 25-29, 33, and 35-38 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

January 4, 2005